

EXHIBIT N

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March 21, 2019

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VIA PRIORITY MAIL

DHHS – OMHA
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Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

BENEFICIARY APPEAL

RE: Request for ALJ Hearing

Beneficiary: Anniken Prosser
W2973 Farmstead Dr.
Appleton, WI 54915

Dates of Service: 1/16/2018; 2/16/2018; 3/16/18; 4/16/18

HICN: 4R87U71QM75

Medicare Appeal No: 1-8175102470

Date of QIC Decision: Jan. 18, 2019

Device: Tumor Treatment Field Therapy (E0766)

Supplier: Novocure, Inc.

Our Ref: 19-51

Dear Claims Coordinator:

As an authorized representative of the above-captioned Medicare beneficiary, Anniken Prosser, I hereby appeal to an Administrative Law Judge the above-captioned decision rendered by the Qualified Independent Contractor (“QIC”) C2C Innovative Solutions, Inc. for the claims submitted for tumor treatment field therapy (“TTFT”) for a glioblastoma. The QIC denied the claim asserting that there is insufficient documentation to quantify the effects of the device and the published studies do not clearly document the effectiveness of the device. The QIC generally referenced LCD L34823.

Ms. Prosser was diagnosed with a glioblastoma in July 2015. She had surgery and was treated with radiation and chemotherapy. Her clinician also prescribed TTFT. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, a device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. During the clinical trial for newly diagnosed glioblastomas, such as that of Ms. Prosser, the TTFT results were so compelling that at the interim analysis, the Data Safety Monitoring Board recommended that those not receiving TTFT be able to cross over to receive the treatment. The FDA agreed. Thus, the peer-reviewed literature more than adequately reflects the effectiveness of the treatment.

The published, peer-reviewed literature shows the improved clinical survival and the progression-free survival of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network ("NCCN") guidelines and is considered the standard of care for newly diagnosed glioblastoma. Hundreds of treating physicians, in all 50 states, have prescribed TTFT. TTFT is covered by all the large national payers. It is used in 59 of the 62 NCD-designated cancer centers. Medicare has paid for numerous claims for medically indistinguishable beneficiaries.

Finally, the DMAC medical directors have already indicated that the LCD does not apply to newly diagnosed glioblastoma, i.e., it is inapplicable to Ms. Prosser's case. In either event, because the 21st Century Cures Act requires the Medicare contractors to list all the evidence considered in support of the LCD, the LCD does not reflect consideration of the any literature, including the most current literature, the LCD is not entitled to deference. Further, a recent production of all the evidence upon which LCD L34823 is based, shows that the LCD has not been kept current with the scientific and clinical evidence. In fact, the LCD record shows that the medical directors have failed to consider any of the peer-reviewed literature, regulatory approvals, technology assessments, indicia of widespread adoption, that evolved after 2014 – a shocking five-year failure for a fatal illness. An LCD which conflicts with the standard of care must be "based on sufficient evidence to convincingly refute evidence presented in support of coverage." No such evidence exists.

Yours very truly,



Debra Parrish on behalf of
Ms. Anniken Prosser

Enclosures:

Attachment A: Appointment of Representative Form

Attachment B: Certificate of Service

Attachment C: CD containing - clinical studies, NCCN guidelines 2013 & 2016 - 2018, payer policies, FDA approvals, statement of adoption, article on clinical trial being stopped, list of patents, prior favorable ALJ decisions (*CD v.17*)

cc: Ms. Anniken Prosser
Novocure, Inc., c/o Justin Kelly

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April 29, 2019

VIA PRIORITY MAIL

Judge Joseph Grow
Office of Medicare Hearings and Appeals
Miami Field Office
51 SW 1st Avenue, Suite 1536
Miami, FL 33130-1608

**RE: Prehearing Brief
ALJ Appeal No. 1-8390277469
Appellant/Beneficiary: A. Prosser
Service: E0766
Dates of Services: 1/16/18, 2/16/18, 3/16/18, 4/16/18
Hearing Date: 5/20/2019
Our Ref. No.: 19-51**

Dear Judge Grow:

In anticipation of the scheduling of the hearing for the above-captioned case, please find attached a prehearing brief to assist in your analysis.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish
Attorney for A. Prosser

Enclosures:
Prehearing Brief

cc: Ms. Prosser